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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,839	12/21/2001	Richard Derosé	022650-685	4793

7590

10/12/2005

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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/023,839

Applicant(s)

DEROSE ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 August 2005 has been entered.

***Status of the Claims***

1. Claim 1 and new claims 2-12 are pending. New claims 2-12 are subject to restriction, as indicated below.
2. All rejections not addressed below have been withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Election/Restrictions***

4. Newly submitted claims 2-12 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The claims are linked by the technical feature of a DNA sequence which is the intron of

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the 5' non translated region of a plant H3.3 gene. However, this feature is not special because it is known in the prior art, see Chaubet et. al., J. Mol. Biol. (1992) vol 225, pages 569-574.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1, an isolated DNA sequence comprising the intron of the 5' non translated region of a plant H3.3 gene.

Group II claim(s) 2-8, drawn to methods for making a chimeric gene, comprising linking to promoters and coding sequences the intron of the 5' non translated region of a plant H3.3 gene.

Group III, claim(s) 9-12, drawn to a chimeric gene comprising the intron of the 5' non translated region of a plant H3.3 gene, operably to promoters and coding sequences, and plants transformed therewith.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Group I claims (claim 1) is examined in the instant action and Group II claims (2-8) and Group III claim(s) 9-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112-written description***

5. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Actions mailed 2 July 2004 and 18 April 2005.

Applicant traverses saying primarily (Response, p. 5) that the only basis on which the Examiner is maintaining the rejection is that Applicant has not "defined the size or size range of the 5' region in which the expected 5' intron would occur". Applicant asserts that "while the size of introns may be variable, the expected range of plant intron size would have been known to a person of ordinary skill in the art and therefore it is not necessary for such to be described herein", citing Sinibaldi, op. cit. Applicant further asserts that "one skilled in the art would have recognized the bounds of any particular plant intron by the conserved splice junction sequence which define the bounds of every plant intron", again citing Sinibaldi, at Tables I and II (Response, ¶¶ bridging p. 5 and p.6).

Applicant's traversal is unpersuasive. Sinibaldi's discussion of Tables I and II (p. 233-234), titled " nucleotide frequencies at the 5' [and at the 3'] splice junctions of

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monocot and dicot introns", states that the "great variability within the proposed consensus sequence of the 5' splice site has prompted some to subclassify the "eukaryotic" intron consensus into separate motifs, ...in an attempt to define patterns necessary and sufficient for recognition of the 5' splice site. Although most monocot and dicot introns can be separated into such categories, enough variability remains to question the usefulness of such a process." See ¶ bridging pages 235-236. Quoting Sinibaldi "there is much variability among different introns, even within the same gene. Examples of authentic introns that appear to conflict with the general consensus rules..can be found". (Page 238, bottom ¶).

Applicant's traversal is unpersuasive. Applicant states that all introns have consensus sequences in the 5' and 3' splice sites and these are known to the skilled person as evidenced by Sinibaldi, 1992. Whereas Applicant has exemplified two H3.3 histones from Arabidopsis in the instant case, Applicant had additional information relating to the Arabidopsis genes—information which was required for this exemplification. This information includes: a single large intron was known to be located in the 5' non translated region of each of the Arabidopsis genes (Chaubet et. al. 1992); Applicant also had information about the size of the 5' non translated region (Chaubet et. al. 1992, p.572).

Applicant cite<sup>s</sup> a recent case, *Capon v. Eshhar v. Dudas*, No. 03-1480 (Fed Cir 2005), saying that "there is no per se rule that sequences of claimed DNA molecules must be given ...in order to fulfill the written description requirement", and that the written description requirement must be applied in the context of the particular invention

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and the state of the art (Response, p. 7). Applicant maintains that Chaubet teaches that corresponding genes exist in other plants, and that the structural features common to plant introns are well understood so that the recited introns could be recognized.

Applicant's traversal is unpersuasive. Applicant has not defined a size or size range of the 5' region in which the expected 5' intron would occur. Sinibaldi, 1992, teaches that introns range in size from 36 bp to greater than 100,000 bp (p. 230). Therefore, thousands of kb of DNA are 5' to the claimed sequence. Nor has Applicant defined a size range of the expected intron. Applicant has provided these descriptions for the two Arabidopsis H3.3 genes exemplified. Applicant's claims, however, are drawn to a DNA sequence which is the intron of the 5' non translated region of a plant H3.3 histone gene, wherein the plant is unspecified and includes the taxonomically divergent species duckweed, palm, orchid, iris, soybean, rice, Eucalyptus and sequoia trees.

***Claim Rejections - 35 USC § 112-enablement***

6. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record set forth in the Office Actions mailed 2 July 2004 and 18 April 2005.

Applicant traverses that the one "of ordinary skill in the art could identify and obtain any 5' intron of a plant H3.3 gene using routine methods...and as further evidenced by the exemplary sequence alignments provided" (Response, p. 8) in Attachment A. Applicant further asserts "it should be noted that under similar

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circumstances in *Capon, supra*, the BPAI presumed and the Federal Circuit did not overturn this presumption (Response, p. 9) .

Applicant's traversal is unpersuasive. Applicant provides (Exhibit A) a BLAST search which "show that the histone H3.3 from rice and vine share 100% identity with the one of *Arabidopsis* from which the intron disclosed in the Examples have been isolated." (Response of 2 November 2004, p. 9, top ¶).

Applicant has provided information on the 5' regions of two H3.3 histone genes of *Arabidopsis*, a dicot angiosperm plant. The sequence information for the two examples given, rice and vine, necessary for this determination was available as of February 2004 and May 2003 respectively (see NCBI accessions AAS19511 and AAP307390). The specification must be complete as of the date of filing, whereas the cited information was not available as of the date of earliest filing date of the instant case (19 July 1995).

See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Furthermore, the introns of Applicant's exemplified SEQ ID NO: 6 and 7 are relatively small, about 400 bp, and are very AT-rich DNA, ca. 71% (*Sinibaldi Table IV*, p. 238) which means that heterologous probes will not hybridize stringently compared to GC-rich regions.

#### **Remarks**

7. No claim is allowed.



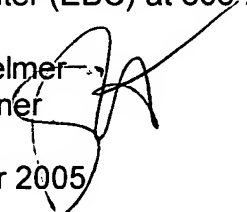
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
30 September 2005



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